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(54) Title: SYNTHETIC FECAL MATERIAL

(57) Abstract

The synthetic fecal material is a viscoelastic analog which simulates natural fecal material, particularly that excreted by young infants. The synthetic fecal material satisfies a particular yield value and zero shear viscosity equation. The equation may be approximated by a linear regression on a log-log scale.

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SYNTHETIC FECAL MATERIAL

FIELD OF THE INVENTION

This invention relates to synthetic fecal material for use in a product development laboratory, and particularly for use in developing disposable absorbent articles.

BACKGROUND OF THE INVENTION

Disposable absorbent articles are well known in the art. Disposable absorbent articles absorb and retain urine and fecal material deposited thereon by the wearer. The wearers of disposable absorbent articles are typically infants and incontinent adults.

Considerable attention has been paid in this art to the collection of fecal material. Much of the art has been specifically devoted to how fecal material may be handled and isolated from the wearer. Examples of such attempts in the art include commonly assigned U.S. Patents 5,171,236 issued December 15, 1992 to Dreier et al. and 4,990,147 issued February 5, 1991 to Freeland.

It will be apparent, however, that the development of such disposable absorbent articles requires a supply of either natural or synthetic fecal material. The natural or synthetic fecal material is helpful in comparing the attributes of various disposable absorbent articles and further refining this art.

A synthetic fecal material is preferable to natural fecal material. Synthetic fecal material raises neither the storage nor bacteriological concerns of natural fecal material, and can be made with precision over time. In contrast, natural fecal material varies widely between individuals. If the natural fecal material is collected from infants, the fecal material will change with the age of the individual. Furthermore, as the individual grows out of diapers, that individual will likely no longer be available to supply natural fecal material. A new source, with the attendant variations he/she introduces, must be obtained.

Prior art characterizations of fecal material do little to aid the understanding of a suitable synthetic fecal material. For example, the prior art discusses the contribution of bacteria from feces to enzymes in the urine. This combination results in the production of ammonia and may lead to diaper rash. The prior art further characterizes artificial feces as blood in water. However, none of such prior art points the way to a synthetic fecal material suitable for use in laboratory development of disposable absorbent articles. Examples of such attempts in the prior art include U.S. Patents 4,219,336 issued August 26, 1980 to Guthlein et al.;

4,297,271 issued October 27, 1981 to Guthlein et al; 4,685,909 issued August 11, 1987 to Berg et al; and 4,842,593 issued June 27, 1989 to Jordan et al.

Clearly there is a need in the art for a synthetic fecal material which can be precisely reproduced between batches and over time, in order that various disposable absorbent articles may be tested under the same set of conditions. It is further apparent there is a need to provide a synthetic fecal material which eliminates the variability and toxicological concerns present in natural fecal material.

Accordingly, it is an object of this invention to provide a synthetic fecal material. Furthermore, it is an object of this invention to provide a synthetic fecal material which can be precisely made from batch to batch, yet fall within a particular range of properties. Finally, it is an object of this invention to produce a synthetic fecal material which simulates the low-viscosity fecal material typically excreted by young infants.

BRIEF DESCRIPTION OF THE DRAWING

While the Specification concludes with claims particularly pointing out and distinctly claiming the present invention, it is believed the same will be better understood from the following description taken in conjunction with the accompanying drawing in which:

Figure 1 is a graphical representation of a two-dimensional area which satisfies two rheological properties necessary for a synthetic fecal material according to the present invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention is a synthetic fecal material. The synthetic fecal material is a viscoelastic analog, particularly a thickening agent in an aqueous medium.

By "viscoelastic," it is meant that the analog has a finite retardation time constant as measured by a creep test. The retardation time constant is the time it takes the structural network within the analog to respond to a step change in an applied stress. A purely elastic material would have a retardation time constant of zero seconds. An analog according to the present invention has a retardation time constant of less than 40 seconds in order to be viscoelastic, and preferably has a retardation time constant of less than 25 seconds.

Furthermore, the analog according to the present invention has a yield value of 7 to 10,000 dynes per square centimeter, preferably has a yield value of 30 to 1,000 dynes per square centimeter, and more preferably has a yield value of 75 to 700 dynes per square centimeter. The yield value is the shear stress necessary to induce a shear rate of 10^{-4} radians per second. The yield value is the principal parameter indicating the synthetic fecal material's tendency to remain in one place and not to flow unless acted upon by a sufficient external force. The yield value may be conceptualized as the stress level below which the sample does not readily flow. Conversely, at stress levels above the yield value the material will flow. In contrast, viscosity indicates the relative speed at which the synthetic fecal material would be expected to flow under an applied stress.

Furthermore, a synthetic fecal material according to the present invention has a zero shear viscosity sufficient to satisfy the equation:

$$\log(\eta_0) = 0.901 \log(\text{yield value}) + (4.717 \pm 0.6),$$

and preferably satisfies the equation:

$$\log(\eta_0) = 0.901 \log(\text{yield value}) + (4.717 \pm 0.3),$$

wherein η_0 is the zero shear viscosity in centipoise, and the yield value is measured in dynes per square centimeter. Of course, the yield value satisfies the constraints specified above.

The first equation is graphically illustrated in Figure 1, which is a log-log graph showing the area in which an analog according to the present invention may occur. It is to be understood that the graph of an analog satisfying the second equation would have one-half of the vertical bandwidth illustrated in Figure 1.

The yield value may be determined by a controlled stress rheometer. A suitable rheometer is available from Carri-Med, division of TA Instruments of Valley

View, Ohio, as model number CSL100. The rheometer utilizes a stainless steel solvent trap cone fixture. The rheometer has a horizontal stationary plate, onto which the sample is placed and a two degree tapered cone suspended above the plate with the axis perpendicular to the plate. The two degree cone is truncated to provide a 54 micron fixed gap between the end of the cone and the plate. The cone is 4 centimeters in diameter, has a rate factor of 28.6 and a stress factor of 0.0597. The cone is connected to a drive shaft for axial rotation. The cone and plate are maintained at 35 degrees C throughout the test.

A suitable sample (typically 2 to 3 grams) of an analog to be tested is placed on the plate and generally centered beneath the axis of the cone. The cone is lowered into position. Excess amounts of the sample which are displaced beyond the diameter of the cone are removed using a spatula.

A programmed application of a shear stress is applied to the sample by the rheometer. The stress is applied so that it results in a deformation of the sample, particularly a rotation deformation which produces a strain rate of 10^{-4} radians per second. The test is terminated if the shear rate exceeds 10 1/seconds. The stress at which a strain rate of 10^{-4} radians per second occurs is the yield value for the sample.

The zero shear viscosity of the synthetic fecal material is determined by the shear stress/shear rate data found in measuring the yield value. The data are fitted to the Cross rheological model using the software supplied with the aforementioned controlled stress rheometer. This software uses a viscosity vs. shear rate relationship having manually input lower and upper limits of 10^{-3} and 10 1/seconds respectively.

The retardation time constant may be found by a creep test using the controlled stress rheometer in the automatic mode. In the creep test a shear stress is applied in a step change and maintained for 90 seconds. The applied stress is 90 percent of the yield value found as described above. The applied stress is removed. The retardation time constant is calculated by the software available with the aforementioned rheometer, using the Berger rheological model. This time constant is less than 40 seconds, and preferably less than 25, seconds for a synthetic fecal material according to the present invention.

The synthetic fecal material according to the present invention is considered to be shelf stable. As used herein an analog is considered to be "shelf stable" if its yield value and zero shear viscosity do not significantly change within the period of 12 hours to 72 hours following its synthesis. The synthetic fecal material described

and claimed hereunder is allowed to equilibrate for at least 12 hours prior to determining whether or not it satisfies the foregoing equations. However, it is not necessary that the synthetic fecal material described and claimed hereunder last more than 72 hours. It is believed that this period of 60 hours is sufficient to allow considerable laboratory testing of disposable absorbent articles to occur. It is further unnecessary to refrigerate the synthetic fecal material according to the present invention.

A suitable synthetic fecal material according to the present invention may comprise a thickening agent in an aqueous medium. The aqueous medium may be water or saline solution. The thickening agent may be an acrylic polymer, preferably an acrylic acid homopolymer, having a weight average molecular weight of about 1,250,000 $\pm$ 250,000. Such an acrylic acid homopolymer may be mixed with water in a solution of about 1.5 to about 6 weight percent, preferably about 2.5 to about 5.5 weight percent, and more preferably about 2.8 to about 5 weight percent. A suitable acrylic acid homopolymer is carboxy polymethylene and carbomer. A particularly suitable thickening agent is available from the B. F. Goodrich Company of Brecksville, Ohio, as Carbopol 941.

In order to simulate certain types of fecal material, particulate matter may be added to the analog. Purdue University research conducted for NASA has resulted in a particulate which is particularly suitable for use in synthetic fecal materials. Such a particulate is available from Silicone Studios of Valley Forge, Pennsylvania, under the tradename Feclone. Four different types of Feclone are available, with Feclone BFPS-6 being most preferred in the present invention. The Feclone may be added in concentrations of about 1 to about 6 weight percent, depending upon the particular amount of thickening agent added to the synthetic fecal material. A synthetic fecal material having about 1.5 to about 3 weight percent Feclone has been found to be particularly suitable for laboratory testing.

Table I illustrates four samples of synthetic fecal material according to the present invention. The first three samples are an analog of 3 to 5 weight percent Carbopol 941 in a solution of distilled water. The fourth sample has 3 weight percent Carbopol 941 and 2 weight percent Feclone BFPS-6 in a solution of distilled water. These samples are designated by the first column of Table I. The second column of Table I gives the yield value of each sample in dynes per square centimeter. The third column gives the zero shear viscosity of each sample in centipoise. The fourth column gives the retardation time constant of each sample in seconds.

TABLE I

WEIGHT PERCENT OF CARBOPOL IN SAMPLE (PERCENTAGE)	YIELD VALUE (DYNES PER SQUARE CENTIMETER)	ZERO SHEAR VISCOSITY (CENTIPOISE)	RETARDATION TIME CONSTAN (SECONDS)
3%	51.3	926,700	26.5
4%	68.2	1,809,000	25.8
5%	132.7	2,264,000	30.8
3% with Feclone	153.9	9,364,000	17.1

From Table I it can be seen that as the weight percent of the thickening agent increased, the yield value similarly increased. However, the addition of the Feclone particulate material had a more significant effect on both the yield value and the zero shear viscosity.

While the foregoing synthetic fecal material has been particularly described, it will be recognized that there are many permutations and variations of such a synthetic fecal material, all of which are within the scope of the appended claims.

What is claimed is:

1. A synthetic fecal material comprising a viscoelastic analog satisfying the equation:

$$\log(\eta_0) = 0.901 \log(\text{yield value}) + (4.717 \pm 0.6)$$

characterized in that the yield value is from 7 to 10,000 dynes per square centimeter,

and preferably said yield value is from 30 to 1,000 dynes per square centimeter;

and more preferably said yield value is from 75 to 700 dynes per square centimeter;

η_0 is the zero shear viscosity in centipoise, and

the analog has a retardation time constant of less than 40 seconds.

2. A synthetic fecal material according to Claim 1 which satisfies the equation:

$$\log(\eta_0) = 0.901 \log(\text{yield value}) + (4.717 \pm 0.3).$$

3. A synthetic fecal material according to Claims 1 and 2 characterized in that said retardation time constant is less than 25 seconds.

4. A synthetic fecal material comprising a viscoelastic analog which satisfies the equation:

$$\log(\eta_0) = 0.901 \log(\text{yield value}) + (4.717 \pm 0.3)$$

characterized in that the yield value is from 7 to 10,000 dynes per square centimeter,

η_0 is the zero shear viscosity in centipoise, and

the analog has a retardation time constant of less than 25 seconds.

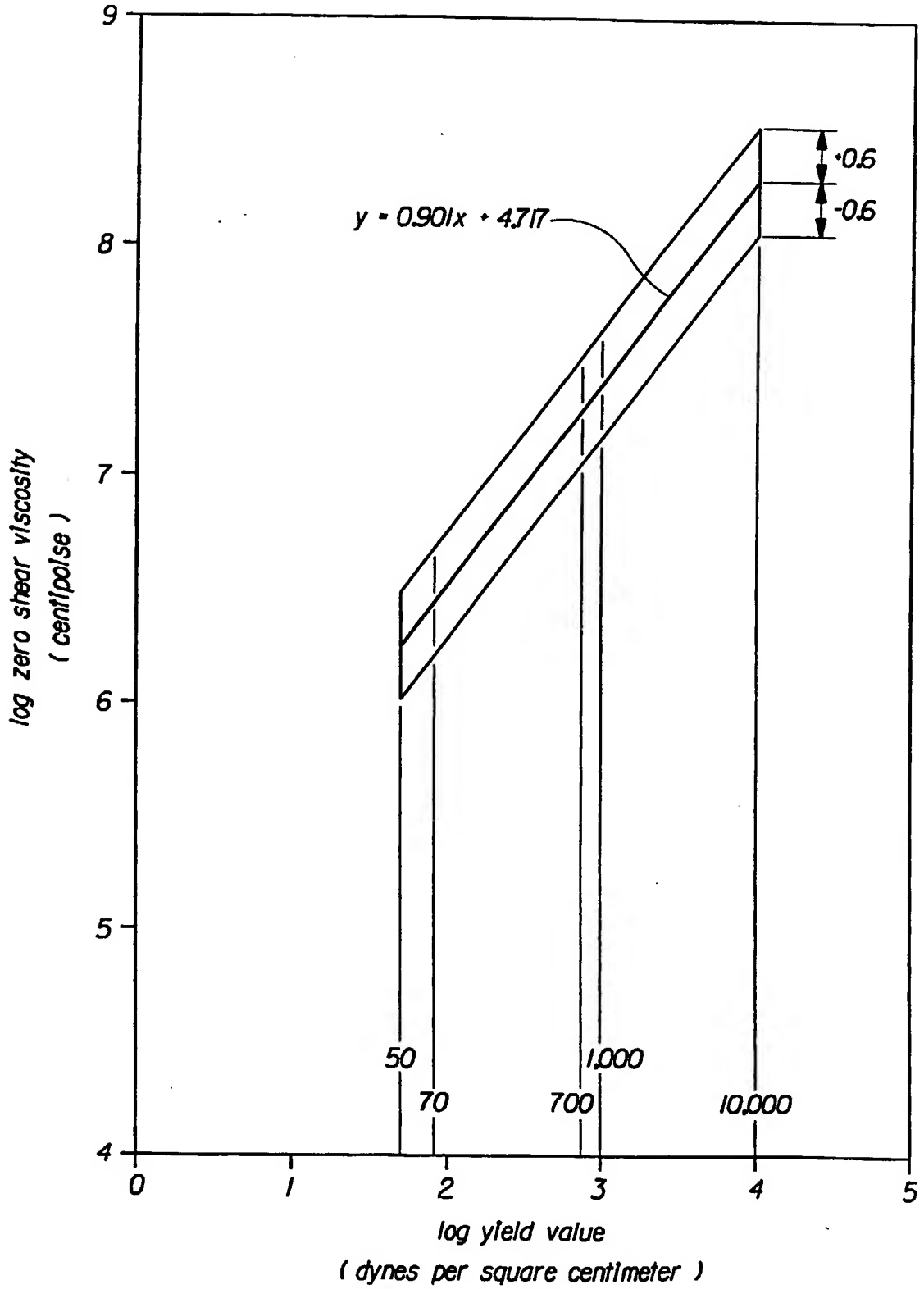
5. A synthetic fecal material according to Claim 4 characterized in that said yield value is from 30 to 1,000 dynes per square centimeter,

and preferably said yield value is from 75 to 700 dynes per square centimeter.

6. A synthetic fecal material according to Claims 1, 2, 3, 4 and 5 comprising an acrylic acid homopolymer.

7. A synthetic fecal material according to Claim 6 characterized in that said homopolymer has a molecular weight of about $1{,}250{,}000 \pm 250{,}000$.

8. A synthetic fecal material according to Claims 1, 2, 3, 4, 5, 6 and 7 further comprising a particulate material.


9
8
7
6
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4
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3
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5
y = 0.901x + 4.717
+0.6
-0.6
50
70
1,000
700
10,000
log zero shear viscosity
(centipoise)
log yield value
(dynes per square centimeter)

INTERNATIONAL SEARCH REPORT

Int ..tional Application No
PCT/US 94/05816

A. CLASSIFICATION OF SUBJECT MATTER
IPC 5 C08L33/02 G01N33/96 G01N33/48

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 5 C08L G01N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE,A,28 19 284 (RÖHM GMBH.) 15 November 1979 see the whole document	1-8
A	FR,A,2 444 693 (H.-J. KNOBLAUCH) 18 July 1980 see the whole document	1-8
A	DE,B,27 24 438 (RÖHM GMBH.) 7 September 1978 see the whole document	1-8

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
19 September 1994	26.09.94
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Authorized officer Griffith, G

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INTERNATIONAL SEARCH REPORT

Information on patent family members

Int .tional Application No
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